

December 3, 2010

Office of Consumer Information and Insurance Oversight  
Department of Health and Human Services  
Attention: OCIO-9986-NC  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: IMEDECS Response to OCIO-9986-NC

To Whom It May Concern:

On behalf of IMEDECS, I would like to submit our comments in response to the above referenced request for information. IMEDECS is a URAC accredited Independent Review Organization. It is also a founding member of the National Association of Independent Review Organizations (NAIRO). The Company has been conducting appeals since its inception in 1999. It has done so directly for fully insured plans, through more than 20 state departments of insurance/health, and for self-insured plans through employer groups or third-party administrators.

IMEDECS' mission is to provide unbiased, independent informed expert medical reviews that resolve disputes or evaluate the quality of care. We believe that it is aligned with the goals of the Patient Protection and Affordable Care Act and its implementing regulations. Therefore, we appreciate the opportunity to comment and would welcome the occasion to meet with OCIO to provide additional insight, as necessary.

I can be reached by phone at 215.631.9123 or by e-mail at [jmuller@imedecs.com](mailto:jmuller@imedecs.com) if you require additional information.

Sincerely,



Joyce Muller, RN, BS, CCM, CDMS, CMCN, BC  
President and CEO

**(1) What accreditation standards currently apply to IROs?**

Currently the only entity that offers accreditation as an Independent Review Organization (IRO) is URAC. IMEDECS was one of the first companies to become URAC accredited as an IRO and has held the accreditation since 2000.

URAC has both Core standards as well as Independent Review (IR) specific standards that each accredited IRO must adhere to. The IR standards are as follows:

IR-1- Initial Case Review

IR-2- Conflict of Interest Process

IR-3- Conflict of Interest Assessment

IR-4- Reviewer Credentialing

IR-5- File Documentation

IR-6- IRO Log

IR-7- Telephone Access

IR-8- Reviewer Qualifications

IR-9- Reviewer Case Selection

IR-10- Medical Necessity Case Processing

IR-11- Experimental/Investigational Case Processing

IR-12- Administrative/Legal Case Processing

IR-13- Additional Information Processing

IR-14- Multiple Reviewer Cases

IR-15- Decision Notice

IR-16- Decision Timeframes

IR-17- Expedited Review Process

**(2) What credentialing standards do IROs require for medical and legal reviewers? Is credentialing required or voluntary?**

Credentialing is a requirement for URAC accredited IROs. IROs either credential their panels themselves or use a credentialing verification organization (CVO). IMEDECS complies with all URAC standards for credentialing. Generally, credentialing follows these steps for clinicians:

1. Prospective reviewers complete the credentialing application, which includes a current Curriculum Vitae (CV), authorization for release of information, affirmation of professional status, non-disclosure agreement, and a general conflict of interest declaration.
2. IMEDECS conducts primary source verification of the following information:
  - Medical education, residency training, and board certification;
  - Medical malpractice, adverse clinical privileges action, adverse licensure action and adverse membership action, and civil judgments;
  - Eligibility for participation in Medicare, Medicaid, and all Federal health care programs; and
  - Current professional licensure.
3. Primary source verification is accomplished through IMEDECS staff communication with state medical boards, Internet and online database queries (where available), and written privileging documentation from the practitioner's primary clinical inpatient facility.
4. The Medical Director analyzes the information received from the prospective reviewer and the results of primary source verification and decides whether to accept the candidate as a member of its Medical Review Panel. Approved reviewer candidates are presented to the Quality Assurance Committee.
5. Credentialing documents are maintained electronically in the IMEDECS database and in secured locked files to maintain confidentiality.
6. Recredentialing is conducted every two years or earlier if indicated. Board certification and licensure reports are generated and reviewed monthly between credentialing cycles. Credentialing status is traced via quarterly reports that identify reviewers who will be eligible for recredentialing.
7. Any reviewer whose credentialing file is incomplete at the two-year anniversary date is placed on inactive status until his or her recredentialing is completed.
8. When necessary, IMEDECS may utilize an Emergency Credentialing Process for physicians who have not completed full credentialing, but whose services are required for a particular review. The Emergency Credentialing process includes all of the primary source verifications referenced in steps 2 and 3. When Emergency Credentialing is employed, full credentialing will be performed subsequently.

Credentialing for legal reviewers follows a similar process, including: verification of active practice, verification of current licensure; verification of education; and a query for exclusion or disbarment actions.

**(3) What procedures are currently used by IROs to assure that reviewers do not have conflicts of interest with disputing parties?**

As part of the IMEDECS recruitment, credentialing, and re-credentialing process IMEDECS requires that reviewers disclose potential and actual conflicts of interest that may jeopardize their ability to provide independent, unbiased case reviews and must complete and attest to the information on a General Conflict of Interest Disclosure form. The disclosed information is

captured in the credentialing database, used by the Case Review Managers in case specific recruitment.

Specialty matched reviewers with no general conflicts of interest are recruited on a case-by-case basis to determine availability, expertise relevant to the issue under review, and to screen for material professional, familial, financial, or research affiliations with any of the following: the insurer; any officer, director, or management employee of the insurer; the physician, the physicians medical group that is proposing the service; the facility at which the service would be provided; the development or manufacture of the principal drug, device, procedure, or other therapy that is proposed by the treating physician; or the member. The COI screen is conducted prior to case assignment and the completed case specific conflict of interest disclosure form is stored with each case file.

**(4) What are IROs' current capacity for performing reviews? Does staffing and the time necessary for performing a review differ based on the type of claim (e.g. medical necessity, experimental/investigational treatment, coverage issues, etc.)?**

IMEDECS currently has the appropriate staff and policies and procedures in place to handle an increase in reviews. More than 800 reviewers comprise the IMEDECS Review Panel; ensuring that IMEDECS is able to handle a considerable case volume. The current industry data indicates that approximately 1.3 out of 10,000 enrollees exercise their right to an external review, thus, the number of reviews nationally is relatively low.

Internal IRO staffing is not impacted by review type. The type of review can have an impact on reviewer resources, due to the level of research needed to complete experimental/investigational cases and, occasionally, coverage determinations. However, the primary factor impacting both staffing and reviewer resources is the volume of documentation for review.

**(5) Please describe the type of data collection systems that IROs currently use to conduct analyses, reporting, and tracking of appeals and grievances.**

URAC accredited IROs are required to maintain systems that can track and report on the following measures:

- The date the IRO received the request to conduct an independent review;
- The date the IRO received the initial information packet from the referring entity;
- The date the IRO must receive additional information from the referring entity, consumer, or attending provider;
- A description of the issue to be resolved;
- The name of the referring entity;
- Whether the case was expedited or not;
- The IRO's determination regarding the case;
- The date the IRO's determination was issued; and
- The date the IRO's determination was sent to the appropriate parties.

IMEDECS meets and exceeds these requirements via its Case Review Database (CRDB).

IMEDECS utilizes the CRDB for analysis, reporting and tracking of cases. The case information submitted (the enrollee's name, age, gender, diagnosis, treatment, treating provider, treating facility) populates the CRDB and allows the recruitment and conflict of interest screening of an expert reviewer(s) for the case. Client specified turnaround times are also noted and tracked in the CRDB.

The CRDB is also utilized to track and manage the flow of documents. Upon receipt, documents are scanned and saved to the CRDB. The filename includes the case review number, the type of documentation e.g. records, and the sender e.g., health plan, treating provider, claimant. The documentation of the sender in the filename permits the case review management staff to determine what information needs to be sent to the plan to allow it the opportunity to reconsider its determination. Special handling instructions can also be documented, if a client wishes to have certain materials returned to them, for example.

The IMEDECS CRDB tracks and trends a number of metrics for case processing, ranging from case initialization timeframes to expert report turnaround. These metrics are also used to provide several “triggered” events, such as case deadline warnings to expert reviewers as well as case timelines for the IMEDECS staff. These metrics are continuously monitored and improved, to ensure that a customer’s case review is always completed on time and accurately.

Reviews can be tracked and a report can be run for all pending reviews by due date, health plan, review type, and review time frame. The standard time frame of the review is tracked in the CRDB and includes documenting the date of initiation, date due from the reviewer and date due to the client. Current, updated service time tracking (e.g., due in 5 days) is continuously displayed. Total turnaround time (time from enrollee's request to the health plan prior to referral to IMEDECS) is also tracked. All of this information can also be generated into a report (monthly, weekly, quarterly) as requested.

The CRDB is also utilized as part of the Quality Assurance (QA) process to track and report on:

- Standard and expedited review turnaround times;
- Case review outcomes, including reviewer determinations (approval or denial of coverage), overall trends, and by individual reviewer;
- Case-specific conflict of interest, both overall and by individual reviewer;
- Completeness of credentialing documentation;
- Summaries of case reviews by state and/or client;
- Completeness of conflict of interest documentation and outcomes
- Review outcome analysis based on case diagnoses and therapy/procedure
- Recredentialing status

**(6) Are the current data systems available in a secure, 508-compliant, web-based interactive structure?**

The IMEDECS client portal is 508 compliant. IMEDECS maintains several secure, web-based portals for their clients and reviewers. All portal communication between IMEDECS and their clients/reviewers is completely encrypted using the high-grade connection encryption protocol AES-256. This is the highest level of encryption recommended by Department of Commerce

(FIPS-197).

- (7) What telecommunication systems and consumer technical support systems do IROs currently maintain for consumers (e.g., websites, 24-hour hotlines, helpdesk, and/or translation services for non-English speakers)?**

Due to the nature of external reviews, and that reviews are assigned by a plan or state, contact between IROs and consumers is generally very limited. However, based on the DOL Technical Release 2010-01 process, IROs will notify the consumer (in writing) to identify that the case has been assigned to the IRO for external review and notify them that they have ten (10) business days to submit documentation. Additionally, IROs will provide the consumer with written notice of the decision.

IMEDECS has a toll free line available to consumers twenty-four hours a day, seven days a week to respond to consumer issues. For calls outside of normal business hours, callers can call the after-hours line to speak with an IMEDECS staff member directly. The phone is manned by a staff member at all times. Translation services are available for written correspondence.

- (8) What is a reasonable amount of time for a contractor to become fully operational (have all systems in place to conduct external reviews) after the date of a contract award? What resources would be necessary?**

IMEDECS is fully operational to conduct external reviews; IMEDECS has conducted internal and external appeals since its inception in 1999. IMEDECS Case Review Database and client portal are already in place and new user access can be granted easily. The timeframe for contracting and implementation is dependent upon issues raised with the IMEDECS standard agreement. If the standard agreement is suitable for all parties, implementation can be immediate. During the contracting process, reviews can be conducted on a case by case basis utilizing the IMEDECS case review request form. Based on industry projections related to potential volume as referenced in question 4, additional resources would be unnecessary.

- (9) What considerations must be taken into account to smoothly transition from the current Federal interim external review process to a possible new permanent Federal external review process?**

To accommodate the interim external review process, IMEDECS only made minor modifications to its current process. New letter templates were drafted and additional fields were added to the Case Review Database. If the new permanent external review process is comparable to the interim rules, similar actions would need to be taken. Due to its extensive experience, IMEDECS is able to modify its systems to meet changing regulations with little to no issue.

- (10) Do IROs currently operate nationally or in limited geographic areas? Would IROs that currently serve local areas be able to expand their service areas to possibly include other geographic areas such as other States? Are there any State**

**and/or local licensing requirements?**

IMEDECS conducts reviews on a national basis. Although there are some IROs that operate in a limited geographic area, URAC accredited IROs have the ability to conduct reviews nationally. Some states require IROs to obtain licensure to conduct business if not domiciled in that particular state. However, local licensure requirements vary by state.

**(11) Are there any special considerations HHS and/or DOL should be aware of in considering a specialized contract for urgent care appeals or for experimental and investigational treatments? Would such an approach have an impact on coordination?**

Contracts with IMEDECS include medical necessity reviews, experimental and investigational reviews, coverage determinations, and urgent care appeals; a specialized contract is not needed. If a specialized contract for urgent care appeals or for experimental and investigational reviews was constructed, pricing would be a special consideration. Due to the expeditious timeframe of urgent care appeals and the complex nature of an experimental and investigational review (which involve the consultation of peer reviewed literature), the compensation should be increased. In addition, for urgent care reviews, it is important to have all of the relevant documentation at the start of the review as the twenty four (24) hour timeframe does not allow for additional time to await the records.

**(12) Please describe the difference in standard operating procedures and resources (time, cost, personnel) for appeals that involve only medical necessity and those that involve both medical necessity and coverage questions.**

Appeals involving medical necessity issues are reviewed by a physician. Appeals involving coverage issues are reviewed by an attorney. Cases that involve both medical necessity and coverage questions might involve a physician or an attorney. Often times, appeals involving medical necessity and coverage issues can be resolved by a physician alone. However, in certain circumstances, both a physician and an attorney may be necessary. In these cases the cost of the case will increase due to the need for additional reviewers.

**(13) What data are currently collected by IROs for tracking appeals and conducting analyses?**

In addition to the measures listed under question 5, the following information is collected by IMEDECS in the Case Review Database for tracking appeals and conducting analyses:

- Case demographics (the enrollee's name, age, gender, diagnosis, treatment, treating provider, treating facility)
- Documentation/information relevant to the case
- Due date
- Client information
- Review type
- Review time frame
- Standard and expedited review turnaround times

- Reviewer(s) assigned to a case
- Conflict of Interest information
- Case review outcomes

**(14) What steps are taken to ensure confidentiality and security protections of patient information?**

IMEDECS takes a very proactive approach in managing all of their data privacy and security controls. Security postures are carefully reviewed and revised on a regular basis, to ensure that the most up to date standards currently in the industry are being followed.

IMEDECS treats all of their stored case review data files as Protected Health Information (PHI). These records are maintained in a highly secured environment with access only being allowed to systems and users that are explicitly approved to view them. All file access is strictly controlled through encrypted web application views from our Case Review System. Once uploaded into the Case Review System, a portal system user never has direct access to the actual PHI data file. The portal requests the file from a security file security system, which re-validates the user's permissions to view the file, writes an audit log of the request, and then sends the file to the user. This tiered file-retrieval process ensures a "two-key" validation of users credentials before any PHI data is ever retrieved.

IMEDECS is also fully accredited under URAC's Independent Review Organization accreditation. This IRO accreditation body ensures that all its members adhere to a high industry standard on controls for both information security and data privacy controls.

Access to PHI is limited to the IMEDECS personnel who require access to such information to complete their job functions. Hard copies of case review files are kept in locked cabinets, keys to the files are restricted to the Case Review staff. After the completion of a review, hard copies of case information are scanned and then shredded.

Physical security in the building is provided by a key card electronic access system at the doors. Electronic security is provided by both domain level machine logon authentication and separate account level authentication to our internal systems. The servers are housed separately in a locked, lights-out server room with its own redundant cooling systems and power supplies.

All electronic data is backed up Monday through Friday as part of the normal backup and disaster recovery procedures. Off-site archival of backup media is also a normal part of the backup and disaster recovery policy. In addition to the backups, there exists a live mirror of all database information, to allow for lossless failure and minimal downtime in the event of a server failure.

**(15) Do IROs (or subcontractors) currently conduct evaluations of their operations? Do such evaluations include an assessment of how easy it is for consumers to access and use the external review process in a timely manner? Do evaluations result in quality improvement initiatives? If so, what are some examples of quality improvement**

**initiatives undertaken by IROs?**

External evaluations of IROs and their operations are performed by URAC. As part of the accreditation with URAC, IROs are audited by the organization every 2-3 years. IMEDECS was most recently audited by URAC in 2009, and successfully passed the audit and completed its reaccreditation. URAC accreditation requires IROs maintain a Quality Improvement Program as part of its Quality Improvement initiative.

IMEDECS monitors access to services through its complaint process and its customer satisfaction survey. Access to services comprises a minimal percentage of total complaint volume. Complaints are documented in the Case Review Database (CRDB), ensuring that the complaint is resolved and providing IMEDECS employees an outlet to learn from prior complaints. Complaint data is tracked and reported regularly to the Quality Assurance (QA) committee. Another quality improvement initiative is the grading of expert reports. The IMEDECS Case Review Managers review the reports and assign a numerical grade to measure the quality, clarity, and completeness of a decision. The grades are tracked in the CRDB, which allows IMEDECS to monitor and trend individual reviewer performance and reviewer decisions across like cases, identifying trends that show a lack of medical consensus.

**(16) What specific requirements should be applied to IROs to evaluate progress toward performance goals? What performance goals are the most appropriate?**

Performance goals related to service time compliance and consumer/client access to service are the most appropriate. Performance should not be measured by the review outcome.